DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2014

Scottcare Corporation
Snehraj Merchant
Vice President, Engineering
4791 West 150th St.
Cleveland, Ohio 44135

Re: K142180
Trade/Device Name: TeleSense
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI, DRG
Dated: November 7, 2014
Received: November 10, 2014

Dear Snehraj Merchant,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: **TeleSense (K142180)**

The TeleSense device is intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest cardiac arrhythmia. The device continuously monitors and records the data, automatically records events triggered by an arrhythmia detection algorithm or manually by the patient, and automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician.

The TeleSense is a battery powered device to be used to measure, record, store and/or remotely transfer the Electrocardiogram (ECG) noninvasively in mobile patients. The available data transfer methods are USB and Wi-Fi. TeleSense is not limited to certain patient groups or pathologies; however, the TeleSense is not intended for pediatric use. Examples of applications are:

- Cardiology
- Pulmonary Care
- Home Care
- General Practitioners

Contraindications:
a. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
b. Patients who the attending physician thinks should be hospitalized.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K142180.

Date: July 29, 2014

Submitted by: ScottCare Corporation
Registration No: 1527715
4791 West 150th Street
Cleveland, OH 44135

Contact Person: Snehraj Merchant
ScottCare Corporation
4791 West 150th Street
Cleveland, OH 44135

Manufacturing Site: ScottCare Corporation
Registration No: 1527715
4791 West 150th Street
Cleveland, OH 44135

Trade Name: TeleSense

Common Name: Detector and Alarm, Arrhythmia

Classification: 870.1025
Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Product Code: DSI

Subsequent Product Code: DRG

Legally Marketed Predicate Device(s): ScottCare TeleSentry Wireless Ambulatory ECG Arrythmia Monitor, K092947

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Device Description:

The basic operation of the TeleSense platform is to collect and store multiple channels of ECG data. The TeleSense platform was developed to be used as basic platform for 4 different variants on the product, hereafter called "modes". The electronic platform of the different versions is identical but the different modes have some features added or removed from the electronic platform. The differences are related to features. All versions have the same intended use, intended users and intended environment. The different versions are described below.

1. **Basic Mode (Remote cardiac monitor)**

TeleSense's Basic Mode is the basic version of the product. It is a battery powered portable device to be used to collect, record, store and/or remotely transfer the Electrocardiogram (ECG) in mobile patients, as well as cardiac event data. The device only uses non-invasive sensors. The available integrated data transfer methods are USB and Wi-Fi.

2. **Event Mode**

TeleSense's Event Mode operates as a traditional event recorder. It is a battery powered portable device to be used to collect, record, store and/or remotely transfer manually indicated or automatically detected cardiac events in mobile patients. The device only uses non-invasive sensors. The available integrated data transfer methods are Wi-Fi and USB.

3. **Holter Mode**

TeleSense's Holter Mode operates as a traditional Holter recorder. It is a battery powered portable device to be used to collect, record, store and/or remotely transfer the electrocardiogram (ECG) in mobile patients. The device only uses non-invasive sensors. The available integrated data transfer methods are Wi-Fi and USB. In this version, there is no automatic cardiac event detection.

Significant Physical and Performance Characteristics

Design and Performance:

- Configurable to record and transmit encrypted patient ECG and Event data
- Transmits data over Wi-Fi
- Includes a status interface to give feedback to the user
- Includes a manual event button for marking manual events
- Device includes configurable automatic event detection
- Patient is connected to device with noninvasive skin-surface ECG electrodes
- ECG and event data is sent to a remote server for review or on-demand streaming of ECG

Materials:

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- Device housing made from Ultem HU1000 plastic or equivalent, which meets requirements for flammability and biocompatibility

Indications for Use:

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The TeleSense is a battery powered device to be used to measure, record, store and/or remotely transfer the Electrocardiogram (ECG) noninvasively in mobile patients. The available data transfer methods are USB and Wi-Fi. TeleSense is not limited to certain patient groups or pathologies; however, the TeleSense is not intended for pediatric use. Examples of applications are:

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Substantial Equivalence:

Features	Predicate Device: ScottCare TeleSentry K092947	New Device: TeleSense*
510(k) Number	K092947	K142180
Date Cleared	February 26,2010	TBD
Patient Cable 3-lead	Yes	Yes
Patient Cable 5-lead	Yes	Yes
Patient Cable 12-lead	Yes	No[i]
Lead Off Detection	Yes	Yes
Channel Recording	3, 5 and 12	3[ii]
Monitoring Mode	Continuous	Continuous
Data Transmission	Radio Frequency(RF)	Radio Frequency(RF)
Recording Button	Yes	Yes
Unintentional Erase data Protection	Yes	Yes
Power Loss Data Protection	Yes	Yes
Pre/Post programmable times	Yes	Yes
Number of events	Multiple	Multiple
Patient Manual Activation	Yes	Yes
Silent Recording	Yes	Yes

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Features	Predicate Device: TeleSentry K092947	New Device: TeleSense*
Autotriggering	Yes	Yes
Bradycardia	Yes	Yes
Tachycardia	Yes	Yes
Atrial Fibrillation	Yes	Yes
Auto-Trigger On/OFF capability	Yes	Yes
Transmission Mode (Bluetooth2.0 SPP Profile)	Yes	No[iii]
Transmission Mode (Wi-Fi 802.11 b/g/n)	No	Yes[iv]
RF transmission range	100 meters open space (Bluetooth)	100 meters open space (Wi-Fi)
Bandwidth	0.5 - 100 Hz	0.5-40Hz[v]
Recording Period	30 days	30 days
Input Impedance	>20 MΩ	>20 MΩ

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Features	Predicate Device: TeleSentry K092947	New Device: TeleSense*
Differential Input	+ / - 1mV p-p	±5mV p-p[vi]
Differential Input Range	DC ± 100mV	DC ± 300mV[vii]
Common Mode Rejection (CMR)	92 dB	80dB[viii]
Common Mode Ratio Range	+ / - 1.0 V	+ / - 1.0 V
Battery type	3.7V lithium polymer	3.7V lithium ion
Battery Life	24-36 hours before recharge	50 hours before recharge[ix]
Relative Humidity	25% to 95% RH, nc	25% to 95% RH, nc
SPS	100.200,1000	128, 256[x]
Bits	12 bits	8,10,12 bit[xi]

The Substantial equivalence discussion is further detailed in Volume 12.

*Differences between predicate device and new device are detailed in the endnotes of this document.

Testing Results Summary:

Appropriate testing was conducted in accordance with established design control procedures and regulatory guidance documents. The TeleSense meets the safety, mechanical, electrical, and performance requirements requirements of IEC 60601-1, the emissions requirements of IEC 60601-1-2:2007, and the safety, electrical, and performance requirements of IEC 60601-2-47 Part2.

The internal tests conducted were intended to test the performance of the device and included simulated normal ECG signals and simulated paced ECG signal tests. Data recorded was loaded and analyzed in the HolterCare(K042463) and EventCare (K061780) software. In all tests, the TeleSense produced consistent and acceptable results.

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Conclusion:

The TeleSense and TeleSentry are both intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest cardiac arrhythmia. The device continuously monitors and records the data, automatically records events triggered by an arrhythmia detection algorithm or manually by the patient, and automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician.

The TeleSense conforms to Good Manufacturing Procedures outlined by the FDA cGMP. This device is safe and effective for the application for which it is intended and has been tested to confirm the safety and efficacy of the device. The TeleSense is found to be **substantially equivalent** to the TeleSentry.

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[i] Given the intended diagnostic use, having the 3 channels available from 3 lead provides adequate information in order to obtain the appropriate diagnostic information as required for intended use of the device; the TeleSense is intended to capture tachy, brady, pause, and afib diagnostic data which can be detected from a single channel, and having multiple leads for multiple channels merely provides alternative channels for detection. Therefore, this difference in patient cable has no adverse impact on the safety and effectiveness of the TeleSense relative to the predicate device.

[ii] Given the intended diagnostic use, having the 3 channels provides adequate information in order to obtain the appropriate diagnostic information as required for intended use of the device. The TeleSense is intended to capture tachy, brady, pause, and afib diagnostic data which can be detected from a single channel, and having multiple channels merely provides alternative channels for detection. Therefore, this difference in number of channels has no adverse impact on the safety and effectiveness of the TeleSense relative to the predicate device.

[iii] The predicate device provided Bluetooth for the purpose of updating device firmware and for device configuration—the same functionality is achieved in the TeleSense through a USB connection.
This does not have an adverse impact on the safety and efficacy of the TeleSense relative to the predicate device. Bluetooth communication is not utilized for any diagnostic purpose; therefore there is no impact on the intended diagnostic use.

[iv] Both the predicate and the TeleSense have the capability to send diagnostic information to a remote server through their respective transmission modes. The transmission mode in TeleSense is more favorable than in than that in the predicate because of Wi-Fi's higher availability. The transmission mode has no adverse effect on the intended diagnostic use, and there are no adverse impacts to the safety and efficacy of the device.

[v] The TeleSense product's bandwidth exceeds the AAMI/ANSI EC38 standard (which specifies a bandwidth >30Hz), and therefore will not have an adverse impact on the safety and effectiveness of the TeleSense.

[vi] The specifications and performance of the TeleSense meet those indicated in the EC38 and IEC60601-2-47 standards and therefore will not have an adverse impact on the safety and effectiveness of the TeleSense. The intended diagnostic use if not affected by this specification therefore there is no impact to diagnostic use.

[vii] The specifications and performance of the TeleSense device meet the established standard EC38 and IEC60601-2-47, and therefore will not have an adverse impact on the safety and effectiveness of the TeleSense relative to the predicate device. The intended diagnostic use if not affected by this specification therefore there is no impact to diagnostic use.

[viii] The CMR for the new device, TeleSense, differs from the CMR in TeleSentry but still exceeds the specifications in the AAMI/ANSI EC38 and IEC 60601-2-47 standards, and therefore will not have an adverse impact on the intended diagnostics use, safety, nor effectiveness of the TeleSense.

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[ix] The specifications and performance of the TeleSense device exceed those of the predicate device and therefore will not have an adverse impact on the safety and effectiveness of the TeleSense relative to the predicate device. The time before recharge will not have impact on the intended diagnostic use of the device.

[x] For the intended diagnostic purpose of the device, sampling rates of 128Hz and 256Hz exceeds the adequate sampling rate for capturing sufficient information as limited by the EC38 approved 40Hz bandwidth based on the Nyquist theorem. Therefore, there is no impact to the intended diagnostic use nor the safety and efficacy of the device.

[xi] The TeleSense has the same bit settings available as in Telesentry, but also allows for additional sampling rates as well. In this manner, the specifications and performance of the TeleSense device meet or exceed those of the predicate device and therefore will not have an adverse impact on the safety and effectiveness of the TeleSense relative to the predicate device.